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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,746	03/29/2004	Jacob Guth	05408/100M675-US1	5468
7278 7590 01/21/2010 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770				
EXAMINER				
MARX, IRENE				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,746

Applicant(s)

GUTH ET AL.

Examiner

Irene Marx

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/28/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6-10 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed 10/28/09 is acknowledged.

Claims 1, 4, 6-10, 14-23 are being considered on the merits

Claims 11-13 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6-10, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott *et al.* (U.S. Patent Publication No. 2003/0175232) taken with Paul (U.S. Patent No. 6,149,924), Cavazza *et al.* (EP 0631779), Johnsen (US patent 3,683,939), Vromen (US patent 6,416,759), Yu *et al.* (US patent 5,589,505) and Deckner *et al.* (U.S. Patent No. 5,968,528).

The claims are directed to a topical composition comprising L-carnitine or a salt of carnitine and one or more of hydroxy acids, the proteolytic enzyme papain and/or bromelain, skin lightening agents as topical preparations having a pH of about 6 to about 8.

Elliott *et al.* disclose a topical composition comprising L-carnitine and one or more of proteolytic enzymes, such as the peptidase subtilisin, as topical preparations having a pH of about 6 to about 8 and comprising enzymes having an optimum pH of about 6 to about 7. See, e.g., table at page 16. In addition, Paul discloses topical compositions comprising L-carnitine and a hydroxy acid. See, e.g., col. 3 and 6. Glycolic acid is a preferred hydroxy acid (col. 15, line 16).

The references differs from the invention as claimed in the presence of various other components such as papain and specific skin lightening agents.

However, Cavazza discloses the use of various additives in cosmetic compositions. See, e.g., page 8. In addition, Johnsen discloses that the pH for cosmetics is favorable in the range of 5.5 to 7 (col. 5). In addition, Vromen adequately demonstrates that proteolytic enzymes such as papain are routinely added to cosmetic or topical compositions. See, e.g., col. 2.

With regard to the use of skin bleaching agents, Yu *et al.* adequately demonstrate that it is old in the art to add various materials to cosmetic compositions, such as skin bleaches. See, e.g., col. 2. In addition, Deckner *et al.* teach the specific skin lighteners kojic acid and arbutin (col. 31, lines 40-60). This reference also discloses the use of hydroxy acids such as salicylic, glycolic and lactic in topical compositions. See, e.g., col. 31, lines 1-12. Moreover, the use of carnitine in such compositions is disclosed at col. 24, line 22. Deckner teaches that the pH should preferably be between 5 to 8. (Col. 10, line 15.)

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Elliott *et al.* and Paul containing L-carnitine and α -hydroxy acids by adding papain or bromelain and providing various additives to the cosmetic composition and keeping the pH at between 5.5 and 7, for example, including bleaches, lighteners, etc. as suggested by the teachings of Cavazza *et al.*, Johnsen, Vromen, Yu *et al.* and Deckner *et al.* for the expected benefit of providing an efficient and mild topical composition suitable for rejuvenating ageing skin.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Regarding Elliott, applicant argues that the Elliott reference does not specifically disclose L- carnitine, but rather that racemic carnitine is disclosed. The basis for this statement is unclear, since the reference fails to disclose the use of racemic carnitine specifically. Thus, it cannot be concluded unequivocally that carnitine is not L-carnitine. Similarly, there is no indication in the reference that serine or proline are provided in racemic mixtures, for example.

Therefore, this argument fails to persuade in the absence of objective evidence.

Applicant criticizes Cavazza as providing for esters of L-carnitine. However, this reference is relied upon for the disclosure of various additives to cosmetic preparations. The additives are clearly pertinent to any cosmetic composition whatsoever, including the instant one. Clearly a similar composition is provided.

Applicant argues that a pH of about 6 to 8 has unexpectedly improved exfoliating performance. However, as noted previously, Elliott *et al.* disclose a topical composition comprising carnitine and one or more of proteolytic enzymes, such as subtilisin, which is a peptidase and a suitable additive, as topical preparations having a pH of about 6 to about 8 and comprising enzymes having an optimum pH of about 6 to about 7. See, e.g., table at page 16. Applicant has not demonstrated unexpected results for the use of papain or bromelain as proteolytic enzymes. Moreover, the composition as claimed does not require specific amounts or active enzymes as argued (page 9 of the Response). Therefore, the basis for this argument remains unsubstantiated. In addition, the amount the enzymes in the composition is not part of the claimed invention, except arguably at claims 22-23.. Thus a pH correlation with exfoliation is not material to the invention as claimed, since a composition comprising a specific amount of papain activity, for example, is not the claim designated invention.

Moreover, the only composition comprising papain and L-carnitine at pH 7 is disclosed at Specification [0085]-[0087]. The composition of interest contains specific amounts of L-carnitine and papain and does not appear to comprise one or more hydroxy acids or skin lightening agents the effect of which on pH and exfoliating activity cannot be assessed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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